10-9-92

MRID No. 90070

DATA EVALUATION RECORD

1. **CHEMICAL:** Cypermethrin.
Shaughnessey Number: 109702.

2. **TEST MATERIAL:** Technical Cypermethrin (PP383), with a nominal cis:trans ratio of 53:47; No purity was stated; Batch No. P 25; Material No. YOO334/017/003; a brown viscous liquid.

3. **STUDY TYPE:** Avian Single Dose Oral LD_{50} Test.
Species Tested: Mallard duck (Anas platyrhynchos).

4. **CITATION:** Roberts, N.L., and C. Fairley, 1980. The Acute Oral Toxicity (LD_{50}) of Cypermethrin to the Mallard Duck. Study performed by Huntingdon Research Centre, Huntingdon, Cambridgeshire. Laboratory study #ICI 302/80305. Submitted by ICI Limited, Alderley Park, Cheshire. EPA MRID No. 90070.

5. **REVIEWED BY:**

Marise H. Robbins, M.S.E.S., M.A.
Associate Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: Michael L. Whitten for M.H. Robbins
Date: 3/29/91
Reviewed 10/8/92

6. **APPROVED BY:**

Michael L. Whitten, M.S.
Wildlife Toxicologist
KBN Engineering and
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Signature: Michael L. Whitten
Date: 3/29/91

Henry T. Craven, M.S.
Supervisor, EEB/HED
USEPA

Signature: Henry T. Craven
Date: 10/9/92

7. **CONCLUSIONS:** Based on nominal concentrations, the LD_{50} of cypermethrin was greater than 10000 mg/kg. This value classifies the test material as practically non-toxic to mallard ducklings. Based on bodyweight changes, the NOEL is 1526 mg/kg. The study is scientifically sound but does not meet the requirements for an avian single-dose oral LD_{50} study.

8. **RECOMMENDATIONS:** The registrant should report the purity of the test material used in the study.

9. **BACKGROUND:**

10. **DISCUSSION OF INDIVIDUAL TESTS:** N/A.

11. **MATERIALS AND METHODS:**

A. **Test Animals:** The birds used in the study were young adult mallard ducks (Anas platyrhynchos) obtained from the County Game Farms, Home Farm, Hothfield, Ashford, Kent. All test birds were acclimated to laboratory conditions and observed daily for a 14-day pre-test period.

B. **Test System:** All birds were housed indoors in metal mesh-floored pens measuring 2 m x 1.5 m. Each pen contained a food hopper and automatic drinker. A natural daylight pattern was followed. The temperature was recorded daily with a mean value of 18°C and the ventilation fans were adjusted when necessary. The relative humidity was recorded daily with a mean value of 59%.

C. **Dosage:** 14-day single dose oral LD_{50} test. "All dose levels quoted in the report refer to the compound as supplied." Treatment levels were determined after range-finding tests. Nominal dosages were 1526, 2441, 3906, 6250 and 10,000 milligrams of cypermethrin per kilogram of body weight.

D. **Design:** Groups of ten mallards were assigned to each of the five treatment groups and the vehicle control group. Each treatment or control group contained five males and five females. The birds were offered standard Huntingdon Research Centre Layer diet in meal form obtained from Flowers and Son (Ramsey) Limited, Cambridgeshire, known to contain no antibiotic or other growth promoter. The diet was offered ad libitum with the exception of an overnight starvation period prior to dosing. Water was available at all times.

The test material was dispersed in corn oil. The test birds were dosed with a 90% w/v concentration of test compound in corn oil. The control group was dosed with corn oil only. The compound was administered by oral gavage, one operator holding the bird's beak open and the other administering the test compound using a Ch 14 Nelaton rubber catheter and disposable syringe. Care

was taken to ensure that each bird had ingested all the compound before being returned to its pen.

Each bird was individually weighed 7 and 14 days prior to the test, on day 0, and 3, 7 and 14 days after treatment. Average body weights by sex and group were calculated for each day the birds were weighed (Table 1, attached).

Average feed consumption was determined for each dosage group and the control for 7 Days before the study and days 1-7 and 8-14 after the study began (Table 2, attached).

All birds were observed daily for health and mortality. All birds were examined at termination of the study for gross pathological changes.

E. Statistics: No statistics were presented.

12. **REPORTED RESULTS:** One hour after dosing a female from group 6 (10,000 mg/kg) was found dead. No other mortalities occurred throughout the post-dose observation period and it was not, therefore, possible to calculate an LD_{50} value for cypermethrin. However, the toxicity of cypermethrin to the mallard duck is low, with an LD_{50} value in excess of 10,000 mg/kg. All surviving birds appeared to be in good health throughout the study.

With the exception of the 3906 mg/kg female birds, all groups of birds showed overall bodyweight decreases over the pre-dose settling-in period, Days -7 to 0. These bodyweight changes were within normal limits. Over Days 0-7 birds in the 6250 mg/kg group and 10,000 mg/kg group showed overall bodyweight decreases. Birds in the 3906 mg/kg group showed an overall bodyweight decrease over Days 0-3 and a bodyweight increase over Days 3-7. The remaining groups of birds showed overall bodyweight increases over Days 0-7. All groups of birds showed a bodyweight increase over Days 7-14. All food consumption was within normal limits.

At the termination of the observation period, gross post-mortem examinations showed abnormalities in birds from each treatment group. At 1526 mg/kg, one bird had a pale colored liver. At 2441 mg/kg, two birds had pale colored livers, one had a pale, mustard colored liver and three birds had pale colored livers and kidneys. At 3906 mg/kg two birds had pale colored livers. At 6250 mg/kg two birds had pale colored kidneys and one bird had a pale colored liver. At

the highest concentration, 10,000 mg/kg, one bird had pale colored kidneys.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** "It was not possible to establish an LD_{50} value for Cypermethrin to the Mallard duck. However, its toxicity was shown to be low, with an LD_{50} in excess of 10000 mg/kg".

The report stated that the study was conducted in conformance with Good Laboratory Practice regulations ..."with the exception of possible minor items, none of which is considered to have an impact on the validity of the data or the interpretation of the results in the report." The report was signed by the Study Director and the Director of the Quality Assurance Unit.

14. **REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY RESULTS:**

A. **Test Procedure:** The test procedures were in accordance with Subdivision E - Hazard Evaluation: Wildlife and Aquatic Organisms, and SEP guidelines except for the following deviations:

The purity of the test material was not provided. This must be stated.

The study was conducted under natural light, but the actual photoperiod was not provided.

There was no statement specifying that the birds were from the same hatch and phenotypically indistinguishable from wild birds.

The specific age of the birds was not provided, the report only specified "young adult".

The birds were acclimated for 14 days. The birds should have been acclimated to test conditions for at least 15 days.

The report did not describe how the birds were assigned to groups. Assignment should be random.

The birds should be fasted for at least 15 hours prior to the test. The report states they were fasted "overnight".

B. **Statistical Analysis:** Since only one bird died in the test, the LD_{50} cannot be calculated and is assumed to

be greater than 10000 mg/kg, the highest concentration tested.

C. **Discussion/Results:** This study has several procedural deviations. The most serious deviation is the missing purity of the test material.

The only mortality that occurred was at 10,000 mg/kg, within an hour after dosing. It was not clear whether this bird was necropsied. Although all surviving birds appeared to be in good health, 32% (13 of 40) of the treatment birds had physical abnormalities (discolored liver and/or kidney) when a post-mortem examination was conducted at the end of the test. The distribution among groups of these abnormalities would seem to indicate that the abnormalities were not treatment-related. However, it seems odd that abnormalities were absent in the control birds.

Although the authors stated that the bodyweight changes seen from day -7 to 0 were normal, such changes are unusual. However, since no abnormal behavior was noted, and mortality was limited to a single bird, the weight changes prior to dosing probably do not indicate that the birds were in poor physical condition.

Bodyweight changes after dosing were variable, but were considerably lower in the 2441 mg/kg group than in the control group during days 0 to 3. The reviewer assumes this to be a treatment effect. The NOEL, therefore, was 1526 mg/kg.

With an LD_{50} of greater than 10,000 mg/kg, cypermethrin is considered to be practically non-toxic to mallard ducklings. However, the adverse effects on bodyweight should be considered in any risk assessment of this chemical. Altered growth or development of birds caused by exposure to these concentrations in the wild might result in reduced survival rates.

The study appears to be scientifically sound but does not meet the requirements for an avian single-dose oral LD_{50} study. The purity of the test material must be provided.

D. **Adequacy of the Study:**

(1) **Classification:** Invalid.

(2) **Rationale:** The purity of the test material must be provided.

(3) **Repairability:** The study can be upgraded to core if the registrant can provide the purity of the test material used in the study.

15. **COMPLETION OF ONE-LINER:** Yes; March 27, 1991.

Cypermethrin Review

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